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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,265	08/16/2001	Wolfgang Neuberger	BJA262A	2710

7590 05/19/2003
BOLESH J. SKUTNIK PhD, JD
515 Shaker Road
East Longmeadow, MA 01028

EXAMINER

CONLEY, SEAN E

ART UNIT	PAPER NUMBER
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1744

6

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,265

Applicant(s)

NEUBERGER, WOLFGANG

Examiner

Sean E Conley

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an illumination source within the visible light region of the spectrum, does not reasonably provide enablement for an illumination source in the near infrared region. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification recites that the photosensitizers can be activated by wavelengths prominently present in certain illumination lamps. There is no teaching of using an illumination source in the near infrared region of the electromagnetic spectrum.

3. Claims 6-8, 10, and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, claims 6 and 8 recite the word "bond" and claims 7, 10, and 14 recite the phrase "targeting molecule" which are not enabled by the specification.

Art Unit: 1744

The specification does not give any guidance as to the specific examples of a “bond” or “targeting molecule” that would be used in the instant claimed process. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, Applicants are claiming a method of obtaining surfaces with antimicrobial properties. The nature of the photosensitizing arts is that it involves the use of light activated chemicals (photosensitizers) to sterilize or disinfect articles and objects in order to destroy bacteria that are considered harmful and undesirable. There is no absolute predictability even in view of the seemingly high level of skill in the art. The instant specification does not give any guidance as to the specific examples of a “bond” or “targeting molecule” that would be used in the instant claimed process and they are not considered terms of the art. In order to practice the claimed invention, one skilled in the art would have to speculate which type of “bond” and “targeting molecule” could be used to adhere the photosensitizer molecules to the surface being treated and further attract the photosensitizer molecules to the microbes and bacteria that are to be destroyed. The number of possible chemicals that could be considered a “bond” and

Art Unit: 1744

"targeting molecule" embraced by the claims would impose undue experimentation on the skilled art worker.

Therefore, the broad terminology "bond" and "targeting molecule" is not enabled because the metes and bounds of the possible chemicals that could be used to adhere the photosensitizer molecules to the surface being treated and further attract the photosensitizer molecules to the microbes to be destroyed cannot be ascertained.

Claim Rejections - 35 USC § 103

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-5, 9, and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curry et al. (WO 01/34211 A2) in view of Bonnett et al. (WO 93/00815)

Curry et al. disclose a method and apparatus for using photosensitizers and light to treat chemical and/or biological contaminants on surfaces and in aerosol clouds. The method comprises the step of first spraying the surface to be treated with a photosensitizer aerosol spray. Then, the photosensitized contaminates and pathogens on the surface are illuminated with ultraviolet (UV) light (environmental condition) of

Art Unit: 1744

sufficient intensity to cause photochemical destruction or deactivation of the contaminants (see page 4, lines 19-27). Furthermore, it is disclosed that the photosensitizer spray solution may additionally include surfactants, liquid carrier particles, or diluents and may also be electrostatically charged to increase surface adherence (see page 7, line 8 to page 10, line 31).

However, Curry et al. only discloses exposing the photosensitizer to ultraviolet light and does not teach exposing a photosensitizer to visible or near-infrared light.

Bonnett et al. disclose a method for sterilizing a surface which is characterized in that the surface contains or consists of a polymer composition which includes a photosensitizer capable of catalyzing the formation of singlet oxygen from triplet oxygen under the influence of visible light when that surface is exposed to visible light. The surface preferably consists of a polymer composition which includes the photosensitizer. Furthermore, the surface may be a coated or formed surface of an article. The method for sterilizing a surface according to the invention reduces the standing concentration of bacteria on the surface (see page 4, lines 5-15). The articles may take the form of polymer laminates (plastic sheets) with a photobacterial surface for use in hygienic applications, in which one or more layers of the laminate contains or consists of a polymer composition which includes a photosensitizer (see page 8, lines 21-25). It is obvious to one of ordinary skill in the art that an article having multiple layers with each layer containing a photosensitizer will be protected by the preceding layer from light and oxygen therefore preventing activation of the photosensitizer.

Curry et al. discloses the claimed invention except for exposing a photosensitizer to visible or near-infrared light. Bonnett et al. teaches that it is known to sterilize a surface by contacting the surface with a photosensitizer and exposing the photosensitizer to visible light. It would have been obvious to one having ordinary level of skill in the art at the time the invention was made to modify Curry et al. and use a photosensitizer capable of catalyzing in the presence of visible light, as taught by Bonnett et al. in order to sterilize a surface.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnett et al.

Bonnett et al. disclose a method for sterilizing a surface which is characterized in that the surface contains or consists of a polymer composition which includes a photosensitizer capable of catalyzing the formation of singlet oxygen from triplet oxygen under the influence of visible light when that surface is exposed to visible light. The surface preferably consists of a polymer composition which includes the photosensitizer. Furthermore, the surface may be a coated or formed surface of an article. The method for sterilizing a surface according to the invention reduces the standing concentration of bacteria on the surface (see page 4, lines 5-15). The articles may take the form of polymer laminates (plastic sheets) with a photobacterial surface for use in hygienic applications, in which one or more layers of the laminate contains or consists of a polymer composition which includes a photosensitizer (see page 8, lines 21-25). It would have been obvious to one of ordinary skill in the art that the upper

layer protects the lower layers from light and oxygen therefore preventing activation of the photosensitizer.

Allowable Subject Matter

7. The indicated allowability of claim 13 is withdrawn in view of the newly discovered reference(s) to Bonnett et al.

Applicant's Arguments

8. Regarding claims 1-5 and 9, the applicant argues, "In contrast to the primary art reference, WO 01/34211 by Curry et al., the photosensitizer containing formulation for imparting antimicrobial properties to a surface do not require special ultraviolet (UV) light to be activated; they do not merely sit like dust on the surface to be protected, nor are they electrostatically charged to provide some physical bonding..." Furthermore, the applicant argues, "In truth then, the surfaces are not imparted with antimicrobial properties as much as they are disinfected by the use of photosensitizer formulation applied to the surfaces..." Additionally, the applicant argues, "The UV light taught by Curry et al. can not be stretched to teach activation of the photosensitizer by an environmental condition as taught in the present invention."

9. Regarding the rejection of claims 6-8, 10 and 14, the applicant argues that "Once a chemist knows the surface to be protected and the photosensitizer to be used, it would generally not take undue experimentation to decide what would be the best way

Art Unit: 1744

to bond the photosensitizer to a the surface. There is extensive science on the bonding of pendant acid, hydroxyl, or amino groups to cellulosic, plastic or elastomeric substrates, especially since we are not looking necessarily for optimum bonding.”

Furthermore, the applicant argues that “given a specific bacteria or class of bacteria or other microbes from which a surface needs to be protected from, the art can suggest good examples of materials, e.g. haptens sensitive to harmful bacteria, which should be attached to selected photosensitizers to get a composition useful to practice the present invention.”

Response to Arguments

10. Applicant's arguments with respect to claims 1-5 and 9 have been considered but are moot in view of the new ground(s) of rejection.

The newly applied art, WO 93/00815 to Bonnett et al., discloses a method for sterilizing a surface which is characterized in that the surface contains or consists of a polymer composition which includes a photosensitizer capable of catalyzing the formation of singlet oxygen from triplet oxygen under the influence of visible light when that surface is exposed to visible light. The surface preferably consists of a polymer composition which includes the photosensitizer. Furthermore, the surface may be a coated or formed surface. The method for sterilizing a surface according to the invention reduces the standing concentration of bacteria on the surface. This reference in combination with WO 01/34211 to Curry et al. overcomes the deficiencies cited by the applicant because Bonnett et al. teaches exposing a photosensitizer to visible light, which is present on or in a surface to be treated.

Additionally, the applicant argues that in the reference to Curry et al. the surfaces are not imparted with antimicrobial properties as much as they are disinfected by the use of a photosensitizer formulation applied to the surfaces. The examiner disagrees with this argument because if a surface has a photosensitizer adhered to it then the surfaces are imparted with antimicrobial properties when the photosensitizer is exposed to an activating light even if the surface is being disinfected. Curry et al. teaches this method.

Furthermore, the examiner disagrees with the applicant's argument that "the UV light taught by Curry et al. can not be stretched to teach activation of the photosensitizer by an environmental condition as taught in the present invention." An environmental condition can be read in its broadest sense to be any condition located in the environment of the photosensitizer that activates the photosensitizer. Therefore, ultraviolet light can be read to be an environmental condition as claimed.

11. Applicant's arguments with respect to claims 6-8, 10 and 14 are not persuasive.

The examiner disagrees with the applicant's argument that "once a chemist knows the surface to be protected and the photosensitizer to be used, it would generally not take undue experimentation to decide what would be the best way to bond the photosensitizer formulation to the surface." Specifically, there are numerous types of photosensitizers and surfaces to be treated and a chemist would not just know what type of bond to use because of the multitude of possibilities without some quantity of

experimentation. If the bonding of a photosensitizer to a surface is so well known to a chemist that it "would be straightforward" as the applicant states then the bonding limitation of the dependent claims is not be considered to be a novel or inventive step.

Furthermore, the applicant argues that "given a specific bacteria or class of bacteria or other microbes from which a surface needs to be protected from, the art can suggest good examples of materials, e.g. haptens sensitive to harmful bacteria, which should be attached to selected photosensitizers to get a composition useful to practice the present invention." While the examiner agrees that various anti-bodies, gram-negative bacteria sensitive species, etc. are well known, the examiner disagrees with the assertion that given a bacteria one would know exactly what "targeting molecule" to use without experimentation. Given the multitude of various types of bacteria, selecting a "targeting molecules" would require undue experimentation in order to make or use the applicant's invention. The phrase "targeting molecule" encompasses a great number of possibilities and one skilled in the art would have to speculate which "targeting molecules" could be used in the claimed invention. If the art would provide "good examples" of targeting molecules as the applicant has stated, then why are there not any examples disclosed in the specification.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Conley, whose telephone number is (703) 305-2430. The examiner can normally be reached on Monday-Friday 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920. The Unofficial fax phone number for this group is (703) 305-7719. The Official fax phone number for this Group is (703) 872-9310.

When filing a FAX in Technology Center 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite the processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [robert.warden@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, whose telephone number is (703) 308-0661.

SEC



April 30, 2003



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